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MAKI, S	

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1301

DATE MAILED: 01/04/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9-19-94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ☒ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 42-58 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 26-41 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 42-58 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1) Claims 42-58 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42 and 50 are indefinite because the recitation of "coextruding, in combination, a lamination" is confusing. It is suggested to appropriately amend claims 42 and 50 to recite --co-extruding an outer layer and an inner layer wherein the outer layer consists essentially of ..."

2) The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

3) Claims 42-49 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy.

Wang et al[1], directed to the catheter art, discloses coextruding a tube wherein the coextruded tube has an outer layer and an inner layer and forming the tube into a balloon such that the outer layer is biaxially oriented and the inner layer can be heat bonded to a catheter. The outer layer may be made from polyethylene terephthalate and the inner layer may be made from polyethylene. At columns 5 and 6, Wang et al discloses heating the tube, drawing it and expanding it, but does not specifically disclose heating and drawing the balloon so that it exhibits a burst strength greater than seven atmospheres.

Levy, also directed to the catheter art, teaches heating a polyethylene terephthalate tube, drawing the tube and radially expanding the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm).

As to claim 42, it would have been obvious to heat the coextruded tube of Wang et al, draw the coextruded tube and radially expand the coextruded tube so the outer layer is biaxially oriented and the balloon has a burst pressure of at least 200 psi (13.6 atm) since (a) Wang et al and Levy both

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[1]Wang et al (US Patent 5,195,969) is prior art under 35 USC 102 since (a) US Patent 5,195,969 was filed before the filing date of this application and (b) none of the claims in this application are entitled to benefit of the filing date of application 07/411,649. It is noted that none of the claims in this application are fully supported by the disclosure of the 07/411,649.

disclose forming a balloon for a catheter from a tube and (b) Levy suggests that a biaxially oriented balloon, which was made by heating a tube, drawing the tube and radially expanding the tube and which has a burst pressure of at least 200 psi (13.6 atm), is especially useful in medical dilation procedures. The limitation of expanding in a blow molding fixture would have been obvious in view of Levy's teaching to expand in the apparatus as shown in figure 1.

The limitation of claims 43 and 44 would have been obvious in view of Wang et al's teaching to melt the inner layer of the balloon to heat bond the balloon to a catheter tube. It appears that claim 43 does not require the use of a separate adhesive. IN ANY EVENT: it would have been obvious to adhere the balloon with a separate adhesive since it is taken as well known/conventional in the catheter art to adhere a balloon to a catheter body with an adhesive and Parker teaches that coextruded layers may be adhered to a substrate with or without an adhesive. The limitation of the material of the outer layer as set forth in claims 47-49 would have been obvious in view of Wang et al's teaching that the material of the outer layer may be polyethylene terephthalate. The limitation of claim 46 would have been obvious in view of Wang et al's teaching to make the outer layer out of polyesters or polyamides and to melt the inner layer instead of the outer layer during heat bonding of the balloon to

a catheter. The limitation of the bonding material as set forth in claims 45 and 47 would have been obvious in view of Wang et al's teaching to make the inner layer out of polyethylene.

4) Claims 50-58 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy as applied above and further in view of Merrill and Lambert.

Wang et al does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claim 50, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic since (a) Wang et al teaches bonding the balloon which comprises the outer layer to a catheter tube to form a catheter and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

The limitation of claim 53 would have been obvious in view of Merrill teaching to use N-vinyl pyrrolidone as a hydrophilic

material. The limitations of claims 51 and 54-58 would have been obvious for the reasons given above with respect to claims 43 and 45-49. The limitation of claim 52 would have been obvious in view of Wang et al's teaching to melt the inner layer of the balloon to heat bond the balloon to a catheter tube and to melt the inner layer instead of the outer layer during heat bonding of the balloon to a catheter.

5) Claims 42-48 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Dyke, "Coextruded composite film" by Parker and either JA 53-45353 or Wiggins et al.

Levy, directed to a balloon for a catheter, discloses extruding a tube of polyethylene terephthalate, heating the tube and drawing the tube and inflating the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm). At col 4 lines 45-50, Levy discloses fabricating the balloon catheter comprising the balloon by means of conventional techniques.

Dyke, directed to a balloon catheter, teaches forming a balloon with integral thermoplastic bands and sealing the balloon to a catheter tube by fusing the thermoplastic bands with heat.

Parker, directed to coextruded composite film, teaches bringing a first layer and second layer of polymers into contact in a single die while they are still in a molten state, extruding the layers from the die to form a tube and inflating the tube

with air to stretch the tube to a desired thickness. Parker teaches bonding takes place inside the extruder die head and the film leaves the die as a completely multilayered structure. Parker et al teaches that by providing the second layer a "good sealing film" having the all the desired properties of the first layer can be obtained. Parker specifically discloses: "All coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exits in another film." Parker lists "[a]dhesion to other substrates with or without adhesives" as being one of the "property advantages offered by specially tailored coextruded composite films"

JA 53-45353, directed to a stretched double layer film teaches melting two different resins, extruding them to form a laminated tube and then inflating the tube to stretch it to form a biaxially oriented double layer tube having good heat sealablity.

Wiggins et al, directed to forming a tube having an oriented layer and a heat sealable layer, teaches heat sealing an oriented film results in heat seals which are weak and not smooth since orientation is adversely affected by heat. Wiggins et al teaches coextruding two types of plastic to form a tube and then inflating the tube to form a tube which has an oriented layer and is heat sealable at lower temperatures.

As to claim 42, it would have been obvious to coextrude the plastic material described by Levy with heat sealable plastic material to form a double layer tube before the steps of heating the tube, drawing the tube and radially expanding the tube to form the balloon since (a) Levy teaches fabricating a catheter comprising the balloon using a conventional technique, (b) Dyke suggests providing a double layer balloon having an outer layer and an inner heat sealable layer (two bands) so that a catheter comprising the balloon can be fabricated by sealing the balloon to a catheter tube with heat, (c) Parker suggests coextruding a low melting point plastic material with a high melting point plastic material in order to form a double layer tube which has good sealing properties and is virtually free from pinholes and (d) either (i) JA 53-45353 teaches extruding two different plastic materials to form a double layer tube and inflating the tube to form a biaxially oriented tube having "good heat sealablity and flexibility" or (ii) Wiggins et al teaches extruding different plastic materials to form a tube and inflating the tube to form an oriented tube which may be sealed at a lower temperature. The limitation of expanding in a blow molding fixture would have been obvious in view of Levy's teaching to expand in the apparatus as shown in figure 1.

The limitation of claims 43 and 44 would have been obvious in view of Dyke's teaching to heat the inner layer (heat sealable

bans) of the balloon to fuse the balloon to a catheter tube. It appears that claim 43 does not require the use of a separate adhesive. IN ANY EVENT: it would have been obvious to adhere the balloon with a separate adhesive since it is taken as well known/conventional in the catheter art to adhere a balloon to a catheter body with an adhesive and Parker teaches that coextruded layers may be adhered to a substrate with or without an adhesive. The limitation of the material of the outer layer as set forth in claims 47-49 would have been obvious in view of Levy's al's teaching that the biaxially oriented material of the balloon may be polyethylene terephthalate. The limitation of claim 46 would have been obvious in view of (a) Levy's teaching to make the biaxially oriented material out of polyethylene terephthalate (a polyester) and (b) Parker and either JA 53-45353 or Wiggins et al's teaching to make one of the layers of a tube out of a material which has a lower melting point than the material of another layer. The limitation of the bonding material as set forth in claims 45 and 47 would have been obvious in view Parker's teaching to make a sealable layer out of polyethylene, JA 53-45353's teaching to make the heat sealable layer out of polyethylene or Wiggins et al's teaching to make the heat sealable layer out of ethylene vinyl acetate.

6) Claims 50-58 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Dyke, Parker and either JA 53-

45353 or Wiggins et al as applied above and further in view of Merrill and Lambert.

Levy does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claim 50, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic since (a) Levy teaches fabricating a catheter comprising the balloon and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

The limitation of claim 53 would have been obvious in view of Merrill's teaching to use N-vinyl pyrrolidone as a hydrophilic material. The limitations of claims 51 and 54-58 would have been obvious for the reasons given above with respect to claims 43 and 45-49. The limitation of claim 52 would have been obvious in view of Dyke's teaching to heat the inner layer (heat sealable bans) of the balloon to fuse the balloon to a catheter tube and

Parker and either JA 53-45353 or Wiggins et al's teaching to make one layer of a tube out of a material which has a lower melting point than the material of another layer.

7) REMARKS

Applicant's arguments filed 9-19-94 have been fully considered but they are not deemed to be persuasive.

With respect to the application of Wang et al, applicant notes that this application is divisional application of 07/727,664, filed 7-9-91 which in turn is a continuation in part of 07/411,649 filed 9-25-89. Applicant argues that the only details missing from the original specification (07/411,649) involve cataloging the specific names of certain materials and that the Wang et al reference is not relevant to the material added in the continuation-in-part application. In response, the examiner first notes that "[a]ny claim in a continuation in part application which is directed solely to subject matter adequately disclosed under 35 USC 112 in the parent application is entitled to the benefit of the filing date of the parent application. However, if a claim in a continuation in part application recites a feature which was not disclosed or adequately supported by a proper disclosure under 35 USC 112 in the parent application, but was first introduced or adequately supported in the continuation in part application such a claim is entitled to only the filing date of the continuation in part application". See MPEP 201.11

page 200-17 Rev. 15, Aug 1993. Second, the examiner notes that none of claims 42-58 are directed solely to the subject matter adequately disclosed in 07/411,649. For example, claim 47 is not entitled to the benefit of the filing date of 07/411,649 since 07/411,649 fails to support using PEEK as the outer layer. Another example: claim 42 is not entitled to the benefit of the filing date of 07/411,649 since 07/411,649 fails to support the limitation of "the inner bonding layer further being one which adheres readily to a catheter body using a method selected from the group consisting of melt bonding and glue adhesion or a combination thereof". Since claims 42-58 are not entitled to the benefit of the filing date of 07/411,649, the filing date of Wang et al is before the effective filing date of this application and accordingly Wang et al is available as prior art under 35 USC 102.

Applicant's arguments regarding the rejection which uses Levy as a primary reference is not persuasive since Levy recognizes that the balloon must be attached to a catheter, Dyke suggests attaching a balloon to a catheter by bonding the balloon to the catheter with a second heat sealable layer and the remaining secondary references teach that is well known/conventional in the bonding art to coextrude two layers in order to provide a heat sealable layer. Advantages given by Parker for coextruding include adhesion to other substrates with

or without adhesives and freedom from pinholes. These advantages are relevant to a catheter balloon since as noted above Dyke suggests adhering a balloon to a catheter and Levy teaches that a balloon is to be inflated. It is also noted that Levy, JA 53-45353 and Wiggins are all directed to forming oriented tubes and that Dyke, JA 53-45353 and Wiggins are directed to providing a heat sealable layer on a tubular member.

As to Lambert and Merill, the examiner notes that Lambert teaches that it is desirable to provide a polymeric surface of a medical device with a hydrophilic coating so that it will have a low coefficient of friction when wet.

Saab (filed 5-15-90) is cited of interest to show forming a multilayer balloon.

The prior art filed 9-26-94 has not been considered since the information disclosure statement was not accompanied by a certification as specified in 37 CFR 1.97(e). It is also noted that the information disclosure statement did not include a concise explanation of relevance of each document listed that is not in the English language.

8) No claim is allowed.

9) Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10) Any inquiry concerning this communication should be directed to Steven D. Maki at telephone number (703) 308-2068.

STEVEN D. MAKI
PATENT EXAMINER
GROUP 1300

12-27-94

Steven D. Maki
December 27, 1994